



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION N
10/024,625	12/18/2001	Ian D. McRury	022956-71 (MIT-239)	3998
21125	7590	11/02/2004	EXAMINER	
NUTTER MCCLENNEN & FISH LLP			PANTUCK, BRADFORD C	
WORLD TRADE CENTER WEST			ART UNIT	
155 SEAPORT BOULEVARD			PAPER NUMBER	
BOSTON, MA 02210-2604			3731	

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/024,625

Applicant(s)

MCRURY ET AL.

Examiner

Bradford C Pantuck

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 and 20-34 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 and 20-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>04/19/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1, 5, 7, and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,488,690 to Morris et al. Regarding Claim 1, 7, and 20, Morris discloses a suture welding system [Column 2, lines 27-33] for fixedly attaching a first length of suture to a second length. Morris also discloses a method of using his welding system. Morris discloses an electrosurgical energy source [Column 3, lines 13-17: “power-supply”], a suture welding device (100) [see Fig. 1], a working end (distal end of device 100), and a suture contacting element (108). Morris discloses both unipolar and bipolar arrangements for his electrodes [Column 3, lines 10-13].

In his bipolar arrangement [Figure 1], he discloses a first electrode (first wire) electrically coupled to the power supply (a battery or other form of power) disposed on the contacting element (108) for providing electrical energy to the suture [Column 3, lines 10-29]. As a part of his bipolar configuration, Morris also discloses a second electrode (second wire) coupled to the battery, which provides a return energy path to the battery. Specifically, Morris describes a “pair of insulated wires” [Column 3, line 26]. Those of ordinary skill in the welding art know that a “bipolar” configuration

Art Unit: 3731

refers to an arrangement in which current travels from one electrode to another as a part of a complete circuit. Suture is put in the gap between the two electrodes and two lengths are attached to each other [Column 2, lines 38-48]. Figures 1 and 2 show the suture in contact with the suture contacting element (108). Although the respective locations of the tips of the wires are not clear from the disclosure, the *suture is certainly capable of being placed between them*. Figure 1 shows the suture between two grasping members and it can be assumed that one wire is in each grasper.

2. Regarding Claim 5, Morris discloses sutures that are thermoplastics such as nylon [Column 1, lines 26-30]. Such materials are “polymer plastics.”
3. Claims 20, 22-24, 25, 26, 29, and 31-34 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,358,271 B1 to Egan et al. Regarding Claims 20 and 29, Egan discloses a method for attaching sutures (16 & 18) by providing electrical energy, a welding device (the whole machine), a working end (the distal end of the machine), and a suture contacting element (32). Egan discloses effecting the weld by various means, and although he mainly explains the ultrasonic embodiment, he also discloses employing “electrical arc discharge” to weld the sutures together [Column 3, lines 21-25; Column 6, lines 9-17]. Electrical arc discharge is when an electrical charge moves from one electrode through the air to another electrode. Electrical arc discharge, therefore, requires two electrodes. Egan

Art Unit: 3731

does not specify which parts of his device would act as the electrodes, but assumedly it would be component (30) and another component.

4. Regarding Claims 22-24 and 31-33, Figures 15A and 15B show the two opposing (interior), which are movable relative to each other (Fig. 15B). The two sutures are shown in close contact and being constrained laterally by the two interior faces of members (32).
5. Regarding Claim 25, pods (32A) prevent the sutures from sliding out distally.
6. Regarding Claims 26 and 34, the sutures are made from polydioxanone [Column 6, line 8].

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1, 3, 4, and 28 are rejected under 35 U.S.C. 103 (a) as being anticipated by U.S. Patent No. 6,277,117 to Tetzlaff et al. in view of U.S. Patent No. 6,174,324 B1 to Egan et al. Regarding Claim 1, Tetzlaff discloses a welding device capable of welding suture having two electrodes (110/120), an energy source ("electrosurgical generator") [Column 6, lines 31-33], and a suture contacting element [Column 1, lines 34-42]. His invention is intended for use in welding body tissue, but is certainly capable of welding suture as well. The working end is end of the device, which grips the material. He does not disclose first and second lengths of suture.

However, Egan teaches that instead of tying suture tips together to form a knot in a surgical procedure, applying thermal energy to melt the two suture tips together

provides some advantages [Column 1, lines 12-15; Column 2, lines 19-21]. Knots can be difficult to form in tight places, and different knots with various tensions can cause damage to the tissue. Conversely, melting the tips together with a machine such as Tetzlaff's would provide uniform tension in various knots and makes the procedure easier for the surgeon to perform. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use Tetzlaff's machine to melt two lengths of suture together, effecting a surgical closure, in order to close a wound effectively and more easily.

8. Regarding Claims 3 and 4, Tetzlaff discloses two opposing faces ("prongs") having a variable gap between them. Each face has an electrode (110/120) on top of it [Figure 2; Column 2, lines 41-48; Column 7, lines 49-58]. Although the stop member (106) [see Fig. 4 especially] prevents the electrodes from touching each other, *lengths of suture are capable of being placed between the two electrode surfaces and held there.*
9. Regarding Claim 28, the suture contacting element has pods (122) that the sutures could be tied onto, thus preventing them from sliding off.
10. Claims 1, 2, 8, and 27 are rejected under 35 U.S.C. 103(a) as being anticipated by U.S. Patent No. 5,342,359 to Rydell in view of U.S. Patent No. 6,174,324 B1 to Egan et al. Regarding Claim 1, Rydell discloses a system capable of welding suture having two electrodes (34/36) [Column 4, lines 65-66], an energy source ("energy source" – see Abstract), and a suture contacting element (distal end of device). His invention is

intended for use in welding body tissue, but is certainly capable of welding suture as well. Rydell discloses a “bipolar” instrument, which means that one of the electrodes will provide electrical current and the other will provide for return of the current to the source when the two electrodes come in contact with each other. He does not disclose first and second lengths of suture.

However, Egan teaches that instead of tying suture tips together to form a knot in a surgical procedure, applying thermal energy to melt the two suture tips together provides some advantages [Column 1, lines 12-15; Column 2, lines 19-21]. Knots can be difficult to form in tight places, and different knots with various tensions can cause damage to the tissue. Conversely, melting the tips together with a machine such as Tetzlaff’s would provide uniform tension in various knots and makes the procedure easier for the surgeon to perform. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use Tetzlaff’s machine to melt two lengths of suture together, effecting a surgical closure, in order to close a wound effectively and more easily.

11. Regarding Claim 2, Rydell’s device uses radio frequency waves [Column 8, lines 1-10; Column 5, lines 58-60].
12. Regarding Claim 8, with reference to Figure 4B, Rydell’s device has a piston (16) that slides and is able to engage suture positioned in the distal hollow of component 34. The piston slides from the position shown in Fig. 4A to the position shown in Fig. 4B [Column 5, lines 24-27]. The suture welding site is the whole hollow space inside member (34) and distal to piston (16).

13. Regarding Claim 27, Rydell discloses a suture contacting element, which is the hollow interior surface of element (34).
14. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,488,690 to Morris in view of U.S. Patent No. 4,052,988 to Doddi et al. Morris does not disclose making suture out of polydioxanone, but Doddi teaches that one ought to make suture for use in the body out of polydioxanone because it has many desirable properties, including strength, smoothness, and pliability. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to make Morris' suture out of polydioxanone because this material has many surgically desirable properties such as tensile strength and pliability, as taught by Doddi.
15. Claims 21 and 30 rejected under 35 U.S.C. 103(a) as being anticipated by U.S. Patent No. 6,358,271 B1 to Egan et al. in view of U.S. Patent No. 5,342,359 to Rydell. Egan does not disclose radio frequency waves as an energy source, but this is a well known alternative energy source to ultrasonic and electric arc discharge, as demonstrated by Column 1, lines 12-18 of U.S. Patent No. 5,342,359 to Rydell. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to use RF energy instead of electric arc discharge, as it is an alternate and analogous means of applying energy in surgical applications.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Response to Arguments

17. Applicant's arguments filed 06/21/2004, with respect to the prior art U.S. Patent No. 6,488,690 to Morris et al., have been fully considered but they are not persuasive. Morris does in fact disclose *two lengths of suture*. Applicant argues that because the two lengths of suture cease to be lengths of suture when they are tied in a knot.

“This amendment distinguishes the claimed invention from Morris because Morris does not use first and second lengths of suture. In Morris, the sutures are tied into a knot prior to being placed in the sealing device, thus creating a single knotted length. In the claimed invention, the first and second lengths of suture are individually placed onto the suture contacting element prior to welding. Thus, the claimed invention is distinguished from Morris because it utilizes two distinct lengths of suture whereas Morris utilizes only one.” [Amendment, page 11]

Art Unit: 3731

In arguing that when two lengths of suture are tied together they cease to be two lengths, Applicant is incorrect. For a knot to be tied, in fact, two lengths of material *must be present*. Applicant *does not claim* that there are *two separate sutures*, but two *lengths* of suture. A length of suture is any portion of a suture. One suture has an infinite number of lengths contained within it.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (571) 272-4701. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Application/Control Number: 10/024,625

Page 10

Art Unit: 3731

BCP
BCP

October 26, 2004

Julian W. Woo

JULIAN W. WOO
PRIMARY EXAMINER